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|---|-------------|----------------------|---------------------------|------------------------|
| 10/605,126  | 09/10/2003  | Andrew M. Hoff       | 1372.23.PRWOUS            | 2125                   |
| 21901   | 7590        | 12/18/2007           |                           |                        |
| SMITH HOPEN, PA<br>180 PINE AVENUE NORTH<br>OLDSMAR, FL 34677 |             |                      | EXAMINER<br>BHATIA, AARTI |                        |
|   |             |                      | ART UNIT<br>4123          | PAPER NUMBER           |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                               |                             |  |
|------------------------------|-------------------------------|-----------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/605,126 | Applicant(s)<br>HOFF ET AL. |  |
|                              | Examiner<br>AARTI BHATIA      | Art Unit<br>4123            |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9.10.2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9.10.2003</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

This is the initial Office action based on the 10/605,126 application filed on 10 September 2003. Claims 1-33, as originally filed, are currently pending and have been considered below.

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-28, drawn to a device and method of electromanipulation, classified in class 604, subclass 20.
  - II. Claims 29-33, drawn to a method of combining two chemical species, classified in class 607, subclass 3.
  
2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are directed to related methods of electromanipulation. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different functions. Invention I is drawn to the electroporation of one substance into tissue, whereas Invention II is drawn to the combination of at least two distinct chemical species *in vivo*. Furthermore, the

inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. During a telephone conversation with Anton Hopen on 6 December 2007, a provisional election was made **without** traverse to prosecute the invention of **Group I, claims 1-28**. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Drawings***

6. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the lines and shading are not uniform, clean, and well defined. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Claim Objections***

7. Claims 27 and 28 are objected to because of the following informalities: "effects" should be replaced with --affects-- in both claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 12-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 12 is drawn to adapting this device for implantation into a patient. How to adapt the device for implantation is not described in the specification.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8, 10, and 19-28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,318,514 to Hoffmann.

With respect to claim 1, Hofmann discloses a device for electromanipulation of chemical species in vivo relative to a target tissue (abstract) comprising: an array base (22) adapted to be placed coincident to the target tissue (column 2, lines 61-63); a plurality of electrode elements (18) secured in spaced art relation on the array base (figures 2 and 3), the electrode elements adapted to be coupled to an electrical source (column 2, lines 49-50).

With respect to claim 2, Hofmann discloses the device of claim 1 wherein the array base is formed of a nonconductive substrate (column 2, lines 39-44).

With respect to claim 3, Hofmann discloses the device of claim 2 wherein the plurality of electrode elements are integral to the base (column 2, lines 39-44).

With respect to claim 4, Hofmann discloses the device of claim 2 wherein the plurality of electrode elements project from the array base towards the target tissue (figure 3).

With respect to claim 5, Hofmann discloses the device of claim 1 wherein the electrode elements that are independently addressable (figure 3).

With respect to claim 6, Hofmann discloses the device of claim 1 wherein the electrode elements are addressable as one or more sets (figure 2).

With respect to claim 7, Hofmann discloses the device of claim 1 wherein the array base is substantially conformable to facilitate contact between the electrodes and the target tissue (column 2, line 43).

With respect to claim 8, Hofmann discloses the device of claim 1 wherein the array base is substantially rigid with a geometric shape adapted to facilitate contact between the electrodes and a corresponding target tissue (column 2, line 43).

With respect to claim 10, Hofmann discloses the device of claim 1 further comprising one or more fluid reservoirs (14) adapted to deliver chemical species to the target tissue (column 2, line 36).

With respect to claim 19, Hofmann discloses the device of claim 1 further comprising: at least one external reservoir adapted to hold chemical species (14); and at least one conduit (32) fluidly coupling the at least one reservoir to the array base



whereby the chemical species are delivered through the at least one conduit to the array base for delivery to the target tissue (column 2, lines 57-60).

With respect to claim 20, Hofmann discloses the device of claim 1 further comprising a thin film of chemical species (20) on the array base whereby the chemical species are delivered to the target tissue when the array base is coincident to the target tissue (column 2, lines 57-60).

With respect to claim 21, Hofmann discloses the device of claim 20 wherein the chemical species are retained within the thin film by absorption means (column 2, lines 57-60).

With respect to claim 22, Hofmann discloses the device of claim 21 wherein the chemical species are released from the thin film by application of an energy means (column 3, lines 4-5).

With respect to claim 23, Hofmann discloses a device for manipulation of chemical species in vivo relative to a target tissue comprising: a nonconductive, conformable array base (22) adapted to be place coincident to the target tissue (column 2, lines 61-63); a plurality of electrode elements projecting from the array base towards the target tissue (figure 3), the electrode elements addressable individually, the plurality of electrodes adapted to be coupled to an electrical source (column 2, lines 49-50); a control means interposed between the electrical source and the plurality of electrode elements and in circuit communication therein (12), the control means adapted to establish an electrical potential between at least two electrodes; and a delivery means adapted to introduce chemical species to the target tissue (column 3, lines 33-41).

With respect to claim 24, Hofmann discloses a method for electromanipulation of chemical species in vivo relative to a target tissue comprising the steps of: placing at least one array base coincident to a target tissue (column 2, lines 61-62), the at least one array base (22) containing a plurality of electrode elements (18), (column 3, lines 5-8); establishing an electrical potential between at least two electrode elements in the plurality of electrode elements; providing a chemical species coincident to the target tissue (column 3, lines 4-5); controlling the electrical potential whereby the chemical species are delivered to the target tissue (column 3, lines 9-19; lines 33-41).

With respect to claim 25, Hofmann discloses the method of claim 24 wherein the electrical potential effects electromigration of the chemical species to the target tissue (column 3, lines 4-5).

With respect to claim 26, Hofmann discloses the method of claim 24 wherein the electrical potential affects electroporation of the target tissue (column 3, lines 20-32).

With respect to claim 27, Hofmann discloses the method of claim 24 wherein the electrical potential affects both electroporation of the target tissue and electromigration of the chemical species to the target tissue in substantially concurrent synchronization (column 3, lines 20-32).

With respect to claim 28, Hofmann discloses the method of claim 24, further comprising the steps of: establishing a predetermined sequence of electrical potentials for the plurality of electrode elements; and executing the predetermined sequence (column 4, lines 10-24).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann (U.S. Patent No. 5,318,514).

With respect to claim 9, Hofmann discloses the device of claim 1 except wherein the electrode elements are spaced together in sufficient proximity to insure that a peak power of less than 1 kilowatt is needed for electromanipulation of the target tissue. Hofmann does teach using a low voltage (with a field strength from about 0.2 kV/cm to about 20 kV/cm) in claim 1, however Hofmann is silent to the spacing of the electrode elements. It would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the electrode elements in order to achieve the desired output from the electromanipulation device.

With respect to claim 11, Hofmann discloses the device of claim 1 except wherein the electrical source (12) is integrated within the array base (12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to integrate the electrical source into the array base, since it has been held that forming in one piece an article which has been formerly in two pieces and put together only involves routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

14. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann (U.S. Patent No. 5,318,514) in view of U.S. Patent 5,501,662 also to Hofmann (Hereafter abbreviated as '662).

With respect to claim 12, Hofmann discloses the device of claim 11 except wherein the device is adapted for implantation into a patient. Patent '662 teaches an implantable electroporation device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the first invention of

Hofmann by making it implantable so that the electroporation device could effectively mediate, in vivo, intracellular drug and gene delivery for a living patient ('662, column 2, lines 10-13).

With respect to claim 13, Hofmann discloses the device of claim 12 further comprising one or more fluid reservoirs (14) adapted to deliver chemical species to the target tissue.

With respect to claim 14, Hofmann discloses the device of claim 13 wherein the chemical species are released from the one or more fluid reservoirs responsive to a predetermined schedule (column 4, lines 10-24).

With respect to claim 15, Hofmann discloses the device of claim 13 wherein the chemical species are released from the one or more fluid reservoirs responsive to a predetermined time (column 4, lines 10-24).

15. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann (U.S. Patent No. 5,318,514) in view of U.S. Patent 5,501,662 also to Hofmann (Hereafter abbreviated as '662) in further view of U.S. Patent 5,284,136 to Hauck et. al.

Hofmann and '662 disclose the device of claim 13 wherein the chemical species are released from the one or more fluid reservoirs responsive to a predetermination. Hofmann fails to disclose this release in response to a metabolic condition. Hauck et. al. teaches that metabolic conditions can be a signal for electrical responses in an electrical biomedical apparatus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Hofmann by

making responsive to metabolic conditions so that the device is effective when it is needed due to a change in the patient's metabolic state (column 2, lines 65-68).

16. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann (U.S. Patent No. 5,318,514) in view of U.S. 2004/0039343 to Eppstein et. al.

Hofmann discloses the device of claim 1 but fails to teach at least one micro plunger adapted to deliver chemical species to the target tissue, whereby chemical species held with the at least one micro plunger are released through the at least one porous electrode element to the target tissue. Eppstein teaches a micro reservoir (figure 24) which is used with an electroporation device for drug delivery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Hofmann by adding micro plungers so that multiple substances can be delivered or analyzed by the electromanipulation device (paragraphs 160, 174).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARTI BHATIA whose telephone number is (571)270-5033. The examiner can normally be reached on Monday-Thursday 8:00am -6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on (571) 272-1130. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AB

/Joseph S. Del Sole/  
Supervisory Patent Examiner, Art Unit 4123